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10/563,688	01/03/2006	Robert J. Holladay	80663.251821	3401
71398 7590 01/22/2010 STEFAN KIRCHANSKI VENABLE LLP 2049 CENTURY PARK EAST 21ST FLOOR LOS ANGELES, CA 90067				
EXAMINER FISHER, ABIGAIL L				
ART UNIT		PAPER NUMBER		
1616				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/563,688

Applicant(s)

HOLLADAY, ROBERT J.

Examiner

ABIGAIL FISHER

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-10, 18-24 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10, 18-24 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of Amendments/Remarks filed on September 11 2009 is acknowledged. Claims 5, 11-17 and 25-34 were/stand cancelled. Claim 1 was amended. Claims **1-4, 6-10, 18-24 and 35** are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

New Objections Necessitated by the Amendments filed September 11 2009

Claim Objections

Claim 1 is objected to because of the following informalities: the word "are" is missing between the words "particles" and "made" in line 5 of the claim. Appropriate correction is required.

New Rejections Necessitated by the Amendments filed September 11 2009

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-10, 18-24 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 introduces new matter as the claims recite the limitation: "entire surface" There is no support in the specification for this limitation. The limitation of: "entire surface" was not described in the specification as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. The specification discloses a surface coating but does not describe the instantly claimed limitation. There is no guidance in the specification to select coat the entire surface of the metallic silver with silver oxide. Applicants directed examiner to paragraphs 34 and 59 of the specification for support for this amendment. Paragraph 34 indicates that there is "a coating of silver oxide" and paragraph 59 indicates that there is "a surface coating". However, neither of these two paragraphs indicates that the "entire" surface coating. There are no drawings which suggest that the entire surface of the particle is coated. A surface coating would include those in which only the top surface of the particles are coated. Since, the instant application does not make it clear that the entire surface coated, this amendment is deemed new matter. Therefore, it is the Examiner's position that the disclosure does not reasonably convey

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that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-10, 18-24 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the entire surface" in line 6. There is insufficient antecedent basis for this limitation in the claim. Specifically, the term surface does not appear in the claim prior to this recitation.

Claim 1 as currently written is vague and indefinite. The claim recites "wherein the entire surface is coated with silver oxide". The claim does not make it clear which component is coated. Is it the polymer or the elemental silver?

Claims 2-4, 6-10, 18-24 and 35 are included in the rejection as they depend on a rejected base claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 1-4, 8-10, 18-24, and 35 under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. (US Patent No. 20030054046, cited on PTO Form 1449) is **withdrawn** in light of Applicants' amendments filed on September 11 2009.

The rejection of claims 6-7 under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. in view of Schonfeld et al. (US Patent No. 4646730) is **withdrawn** in light of Applicants' amendments filed on September 11 2009.

Modified Rejection Based on amendments in the reply filed on September 11 2009

Claims 1-4, 6-10, 18-24, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan et al. (US PG PUB No. 20020051823, cited on PTO Form 1449) in view of Hanke (US PG PUB No. 20020122832, cited on PTO Form 1449) and Hasegawa et al. (US Patent No. 4983385, cited in the Office action mailed on 6/11/09).

Applicant Claims

The instant invention claims a hydrogel composition comprising a hydrophilic polymer dissolved in a composition of silver in water having a total concentration of silver between about 5 and 40 parts per million, said silver in the form of colloidal silver particles having an interior of elemental silver wherein said silver particles are made from a silver electrode in an electrochemical cell, wherein the entire surface coating of silver oxide, wherein the composition manifests antimicrobial properties.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Yan et al. is directed to nanosilver-containing antibacterial and antifungal granules (NAG) and methods for preparing and using the same. The nanosilver particles contain a metallic silver core which is surrounded by silver oxide with a diameter of 1 to 100 nm (0.001 to 0.1 micrometer) (paragraph 0002). The nanosilver preparations comprise an oxidizing agent which is preferably hydrogen peroxide (paragraph 0021 and examples). The hydrogen peroxide is exemplified in 1 % (Table 1). Exemplified particle size of the NAGs is about 25 nm (0.025 micrometers). It is taught that the silver content of the NAGs is about 20 to 100 mg of silver per gram of the NAGs (paragraph 0027). The NAGs are taught as having broad spectrum antibacterial and antifungal activity. The NAGs have bactericidal and fungicidal effects on more than twenty common pathogens including *E.coli*, *Candida albicans*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, etc. (paragraph 0035). It is taught that the NAGs can be used in various healthcare, medicinal and industrial products to disinfect, inhibit the

growth of bacteria or fungi, and/or prevent mold formation (paragraph 0042). The NAGs used in healthcare products include, but are not limited to, ointments, lotions, sprays for treating injuries and/or urns, bacterial and fungal infections including gynecological infections such as vaginitis, among other things (paragraph 0043).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Yan et al. does not specify a silver concentration of between about 5 and 40 parts per million. However, this deficiency is cured by Hanke.

Hanke et al. is directed to anti-microbial body care products. These products are suitable for applications wherein during normal use said product is in contact with human or animal skin and/or mucosa for longer periods of time (paragraph 0010). The products comprise silver nanoparticles dispersed in an organic matrix (paragraph 0013). The amount of the silver nanoparticles in the matrix is from 1 to 200 ppm, more preferably from 10 to 250 ppm (paragraph 0014). Exemplified amounts include 50 to 250 ppm and 25 ppm (examples 4 and 6). The particle size of the silver is from 2 to 10 nm (paragraph 0015). It is taught that absorbent structures which can be utilized as the matrix for dispersing the silver includes super absorbent polymer or hydrogels.

Yan et al. does not specify that the silver can be delivered via a hydrogel. However, this deficiency is cured by Hasegawa et al.

Hasegawa et al. is directed to an ointment base. It is taught that various bases for pharmaceutical preparations or cosmetic have been known. However, when they are applied as pharmaceutical preparations or cosmetics on wet body surfaces such as

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a mucous membrane they have insufficient adhesion to the applied site and insufficient local retentivity (column 1, lines 13-18). The invention of Hasegawa et al. have obtained an ointment base which has sufficient adhesion to an applied site and local retentivity even when it is applied on a wet body surface and provides prolonged action of a pharmacologically active agent or an active agent without the previous arts defects and problems. The ointment base is obtained by combining a hydrogel with certain methacrylate copolymers and a solubilizer (column 1, lines 38-47). The hydrogel is formed by a water soluble polymer and a material selected from the group consisting of water, a polyhydric alcohol and a mixture thereof (column 1, lines 56-60). Exemplified hydrogels include xanthan gum and hydroxypropyl cellulose dissolved in water (examples 2 and 3). The ointment base is suitable to be applied on a wet body surface for example oral cavity, lips, eyes, vagina, etc. The ointment can include pharmacologically active agents such as analgesics such as lidocaine, dibucaine, etc.; antibacterial or antifungal agents such as chloramphenicol, chlorophenol, etc.; anti-inflammatories; growth factors; and other additives such as stabilizers (column 3, lines 24-65).

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Yan et al., Hanke et al. and Hasegawa et al. and utilize the NAGs in a concentration that allows for silver to be present in an amount from 10 to 250 ppm. One of ordinary skill in the art would have been motivated

to utilize silver in this concentration as Yan et al. teach the compositions can be utilized in healthcare products which are applied to the body and Hanke et al. teach that when nanosilver particles are going to be applied to the body for long periods of time these are suitable concentrations that are effective yet don't irritate the skin. Furthermore, it would have been obvious to one of ordinary skill in the art to manipulate the amount of silver depending on the type of treatment desired such that when there is a larger infection, larger amounts of silver would be required in order to kill all of the bacteria.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Yan et al., Hanke et al. and Hasegawa et al. and utilize the hydrogel ointment base of Hasegawa et al. to deliver the silver to the body. One of ordinary skill in the art would have been motivated to utilize a hydrogel as Yan et al. teach the compositions can be utilized to treat fungal infections and can be in the form of ointments and Hasegawa et al. teach that their ointment is advantageous for application to mucosal surfaces such as a vagina because they possess sufficient adhesion and retention when applied to these wet surfaces.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Yan et al., Hanke et al. and Hasegawa et al. to utilize hydrogen peroxide in the invention of Yan et al. One of ordinary skill in the art would have been motivated to utilize hydrogen peroxide as Yan et al. expressly teach utilizing an oxidizing agent in combination with the NAGs and the exemplified oxidizing agent is hydrogen peroxide.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Yan et al., Hanke et al. and Hasegawa et al. and utilize xanthan gum or cellulose polymers as the water soluble polymer for forming hydrogels. One of ordinary skill in the art would have been motivated to utilize these polymers as they are water soluble polymer exemplified by Hasegawa et al. for forming the hydrogels of the ointment.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Yan et al., Hanke et al. and Hasegawa et al. and add additional components such as other antibacterial (antimicrobial) agents and analgesics such as lidocaine and dibucaine. One of ordinary skill in the art would have been motivated to add the analgesics in order to relieve pain. One of ordinary skill in the art would have been motivated to add other antibacterial agents as the compositions of Yan et al. are designed to treat infections. As a general principle it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining them flows logically from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06**.

Regarding the claimed particle size, Yan et al. teach an amount that overlaps that instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. See **MPEP 2144.05 [R-5]**.

Regarding the limitation that the silver particles are made from a silver electrode in an electrochemical cell, the examiner directs applicant's attention to **MPEP 2113 [R-1]**. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The MPEP also indicates that "the structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). The resulting silver taught by Yan has an interior element of silver and a coating of silver oxide. Therefore, it reads on the instantly claimed silver particles. If applicants feel that the silver made by their process is different, then applicants must demonstrate that the resulting silver is different.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant argues that (1) whereas the present invention utilizes a suspension of nanoparticles having a silver core and a surface coated by silver oxide suspended in water, the material of Yan consists of NAGS which are particles of ground up pith on which has been deposited silver particles prior to grinding. It is argued that therefore, one of ordinary skill would recognize that the particles of the present invention are free to diffuse whereas those of Yan are not. Applicant argues that (2) the data of Yan indicates that NAGs are not effect at low silver concentrations. It is argued that paragraph 0063 indicates that the NAGs are 2 to 8% by weight silver. The disinfectants tests of example 2 were conducted using a solution that contained 1 g of NAG in 100 ml. Because the NAG concentration is 2 to 8% by silver, the 100 ml solution contained between 20 and 100 mg of silver as mentioned by the examiner. Therefore it is argued that 20 to 100 mg per 100 ml represents 200 to 1000 ppm silver which is much higher than the instantly claimed amount. Applicant argues that (3) the test of Hanke are less effective than those of the present invention and do not have a silver oxide surface. Applicant argues that (4) one of ordinary skill in the art would at best find the teachings confusing. Paragraph refers to concentration reported in nmol/L to micromole/L whereas paragraph 14 reports the results in ppm. The concentrations reported in molar fashion seem to conflict with the expressed parts per million. It is argued that paragraph 14 states that it is not parts per million of silver but rather particles.

Applicants' arguments filed September 11 2009 have been fully considered but they are not persuasive.

Regarding applicant's first argument, the instant claims are directed to a hydrogel composition. As claimed the composition comprises a hydrophilic polymer dissolved in a composition of silver in water wherein the silver is in the form of colloidal silver particles having an interior elemental silver and a surface coating of silver oxide. While Yan does teach that the silver particle is attached to the surfaces of stalk marrow, this is not excluded by the claims. Additionally, Yan teaches that the NAGs are utilized to inhibit the growth of bacteria or fungi and/or prevent mold formation. Therefore, the compositions possess antimicrobial properties. The difference between Yan and the instant claims are the concentration of the silver and the hydrophilic polymer. However, the examiner maintains that formulation the NAGS into a hydrogel composition would have been obvious as Yan teaches that forms include ointments and Hasegawa et al. teach that their ointment is advantageous for application to mucosal surfaces such as a vagina because they possess sufficient adhesion and retention when applied to these wet surfaces. Applicants have not demonstrated the criticality of the concentration of silver and hydrogel form.

Regarding applicants' second argument, while the examiner agrees with applicant's statement regarding the concentration, applicants have not provided support that the NAGS are not effective at low silver concentrations. "The arguments of counsel cannot take the place of evidence in the record." *In re Schulze*, 346 F.2d 600, 145 USPQ 716, 718 (CCPA 1965), *In re Huang*, 40 USPQ 2d 1685 (Fed. Cir. 1996), *In re De Blauwe et al.*, 222 USPQ 191, (Fed. Cir. 1984). Applicant has not provided any factual evidence establishing that the NAGs will not work at low concentrations.

Furthermore, it is generally noted that differences in concentration do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or dosage is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233, 235 (CCPA 1955). Given that applicant did not point to evidence establishing the criticality of specific ranges or mode of administration of the invention, it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide the motivation to determine where in a disclosed set of ranges is the optimum combination of dosages. The examiner has cited Hanke in support of the notion that one of ordinary skill in the art would manipulate the concentration of silver for applications wherein during normal use said product is in contact with human or animal skin and/or mucosa for longer periods of time to an amount from 50 to 250 ppm. Applicants have not demonstrated the criticality of the claimed concentration of the silver.

Regarding applicant's third argument, in order to establish unexpected results over the prior art composition, one must compare the closest prior art to the instant invention in a side by side comparison. Therefore, in order to show that the cited prior art is less effective applicants must show a true side by side comparison. This means applicant must actually perform the experiment of the cited prior art and compare the results to that of the instant invention to show that the difference is truly unexpected and not a difference in The person performing the experiment, equipment utilized, conditions

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of the experiment (i.e. humidity of the room), etc. Therefore, in order to show that the prior art compositions are less effective, applicant must run and compare their particularly claimed combination to that of the cited prior art.

Regarding applicant's fourth argument, while paragraph 14 does refer to particles, it states silver nanoparticles and paragraph 13 refers to silver nanoparticles as well. Therefore, it would appear both paragraphs are referring to the silver concentration. While, the examiner agrees with applicant that the molar concentration referred to in paragraph 0013 is lower than that of ppm found paragraph 0014, the examples refer to the ppm concentration. Therefore, the examiner maintains one of ordinary skill in the art would reasonably be expected to utilizing the teachings found in paragraph 0014 which is directed to the ppm concentrations as these are the exemplified concentrations.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments or evidence to overcome the rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

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USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-10, 18-24 and 35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 7135195 in view of Burrell et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims a hydrogel composition comprising a hydrophilic polymer dissolved in a composition of silver in water having a total concentration of silver of between about 5 and 40 parts per million, said silver in the form of colloidal silver particles having an interior of elemental silver and a surface of silver oxide wherein the composition manifest antimicrobial properties.

Patent '195 claims a composition of silver in water comprising a concentration of silver of between about 5 and 40 parts per million, the silver in the form of colloidal silver particles having an interior of elemental silver and a surface of silver oxide. The silver particles have a diameter greater than 0.005 micrometers and less than 0.015

micrometers. The composition exhibits antimicrobial properties. Patent '195 claims all the instant limitations in the dependent claims.

Patent '195 does not claim that the composition comprises a hydrophilic polymer and is in the form of a hydrogel. However, this deficiency is cured by Burrell et al. discloses that formulations of silver that are used to treat skin diseases like acne include hydrogels. The polymers utilized to create hydrogels include alginates, guar gum, and cellulose and derivatives (paragraphs 0154-0156 and 0220).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Patent '195 and Burrell et al. and formulate the composition of Patent '195 into a hydrogel. One of ordinary skill in the art would have been motivated to use this type of formulation because both Patent '195 and Burrell et al. are directed to utilizing silver containing compositions for the treatment of various anti-microbial diseases. The treatment of skin diseases such as acne would benefit from a topical application such as a hydrogel. Therefore, when utilizing the silver composition of Patent '195 for the treatment of acne one of ordinary skill in the art would have been motivated to formulate the composition into a hydrogel for easier application to the infected area.

Claims 1-4, 6-10, 18-24 and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 11813408. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims are set forth above.

Copending '081 claims a composition of silver in water comprising a concentration of silver of between about 5 and 40 parts per million, the silver in the form of colloidal silver particles having an interior of elemental silver and a surface of silver oxide. The silver particles have a diameter greater than 0.005 micrometers and less than 0.015 micrometers. The composition exhibits antimicrobial properties. A further limitation is that the composition comprises hydrogel formed by dissolved a hydrophilic polymer into the composition of silver in water. Copending '081 claims all the instant limitations in the dependent claims.

Therefore, the scopes of the copending claims overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

The rejections are maintained since applicant has not made any substantive arguments traversing the rejection.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616